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Certifier	Michael W. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 78N-0038]

Revocation of Advisory Opinion Entitled "FD&C Act Trade Correspondence 61"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; revocation.

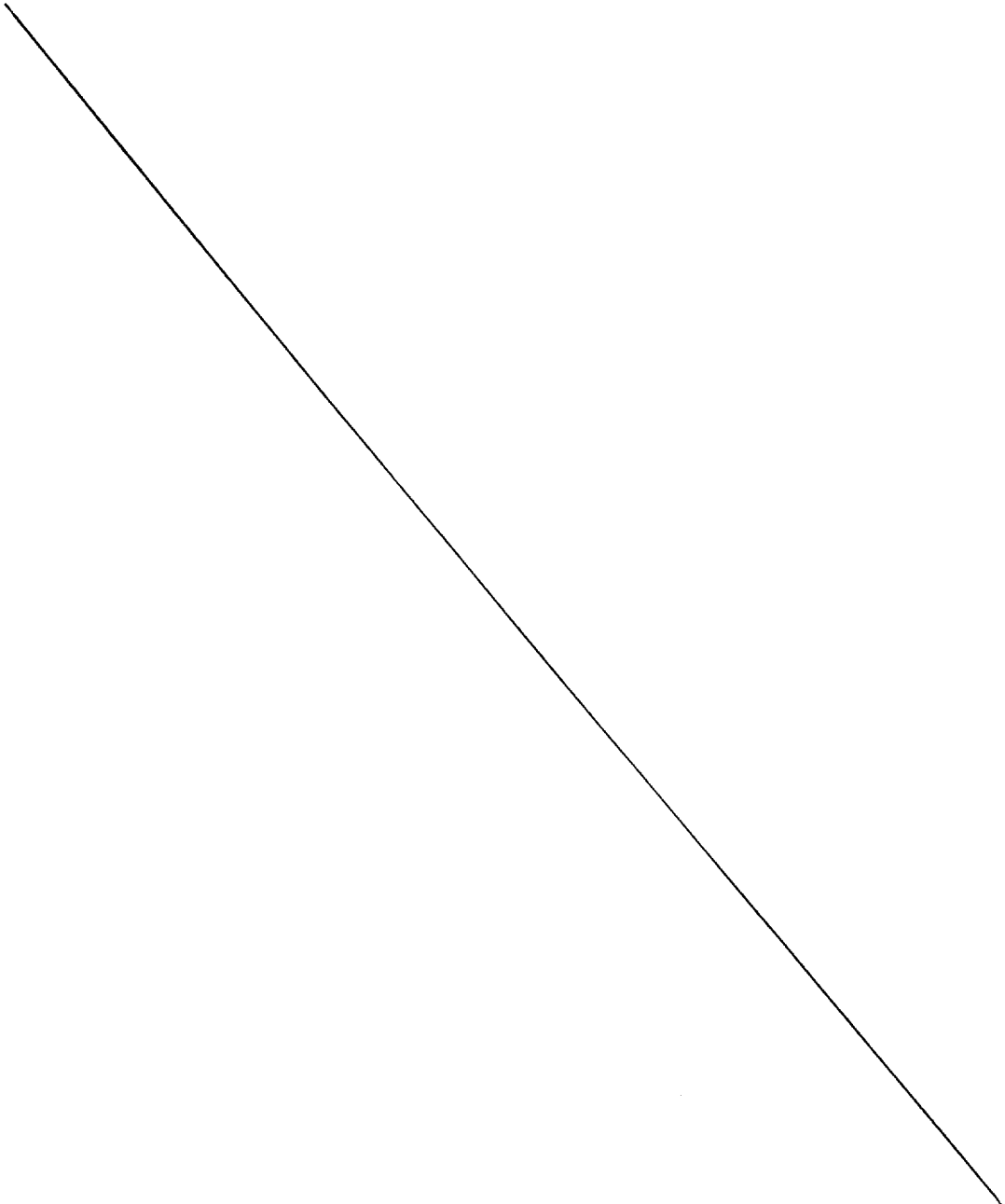
SUMMARY: The Food and Drug Administration (FDA) is revoking an advisory opinion entitled "FD&C Act Trade Correspondence, TC-61," (hereinafter called TC-61) dated February 15, 1940, because it is out of date with current scientific knowledge and is superseded by the final rule for over-the-counter (OTC) sunscreen drug products. As an advisory opinion, this correspondence was not published in the **Federal Register**.

EFFECTIVE DATE: *(Insert date 30 days after date of publication in the **Federal Register**.)*

FOR FURTHER INFORMATION CONTACT: John D. Lipnicki, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

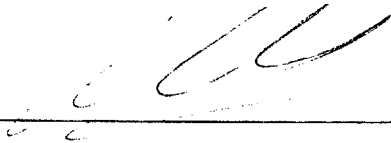
SUPPLEMENTARY INFORMATION: TC-61 is a 1940 advisory opinion regarding the drug and/or cosmetic status of sunburn and suntan preparations. TC-61 states that a product promoted for prevention of damage from the sun is a drug, and a product that is promoted solely for the purpose of acquiring an even tan can be considered a cosmetic. The agency updated this policy in 1976, by stating that a product containing a sunscreen ingredient, even when labeled solely as a tanning aid, is both intended and understood to be a sunburn preventive and, therefore, is a drug under the Federal Food, Drug, and Cosmetic Act (the act).

In the **Federal Register** of May 12, 1993 (58 FR 28194), FDA published a proposed rule for OTC sunscreen drug products. That document included a proposal to revoke TC-61 (58 FR 28204). One comment was received in response to the proposal to revoke TC-61. That comment



did not change the agency's position and is addressed elsewhere in the rule section of this issue of the **Federal Register**. Therefore, under the act and under authority delegated to the Commissioner of Food and Drugs, TC-61 is revoked.

Dated: May 10, 1999
May 10, 1999



William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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